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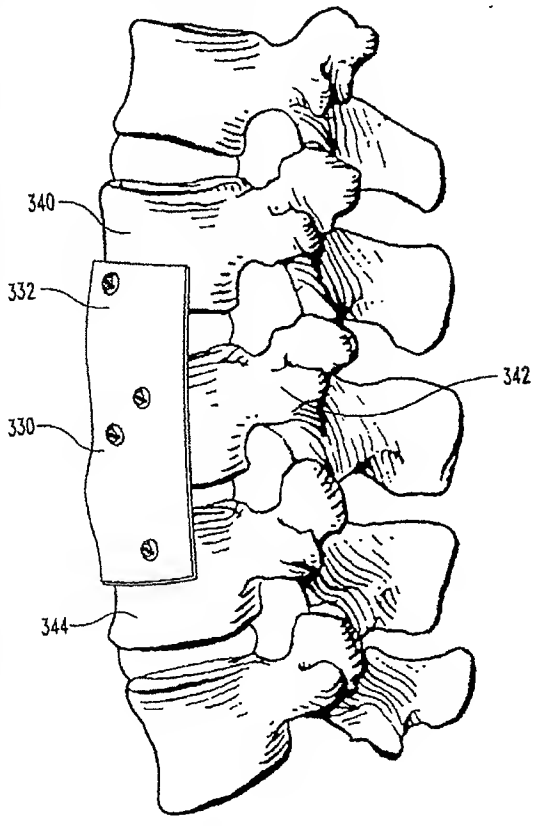

(57) Abstract: This invention relates to a self-forming orthopedic implant (10, 40, 60A/B, 100, 140, 200, 250, 280 and 330). The implant is formed a shape memory polymer. The implant can be provided in an original configuration selected to facilitate orthopedic treatment of bone defects, fixation of bone fragments and fractures, or selected to induce bone structures to conform to a desired anatomical configuration. Non-limiting examples of preferred configurations include bone spacers or bone plates, connective tissue replacements (i.e., tendons, ligaments, and/or cartilage). In preferred forms, the implant is deformed to an alternative configuration prior to implantation. Upon application of selected stimuli, for example, heating the implant to a temperature where the shape memory polymeric material becomes elastic induces the implant to revert to its original configuration. In use, when the implant is subjected to the selected stimuli, it conforms to a selected bone tissue or alternatively conforms to a configuration that urgers bone structures into a desired alignment and/or configuration. When used to replace connective tissues, the implant exhibits a tensile strengh to allow the adjacent bone structure to articulate, yet provides sufficient force to urge the bone structures into a desired position and alignment.

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SELF-FORMING ORTHOPEDIC IMPLANTS

BACKGROUND OF THE INVENTION

This invention relates to an orthopedic implant formed of a shape memory polymeric material (SMP) and to methods of using the implant for orthopedic treatment.

A wide variety of implants are known and used for orthopedic treatment and, in general, for treatment of muscular-skeletal defects. Implants can be made of a wide variety of materials, including metal, ceramic, bone, bone-derived material, polymeric material, and composites. Examples of implants used in orthopedic treatment include the use of bone plates to facilitate alignment and fixation of bone fragments or to bridge fractures. Implants are used as spacers between adjacent bone structures, such as in a disc space between adjacent vertebrae, within cavities formed in bone tissue, for the attachment of prosthetic limbs and/or joint replacement therapy. Typically implants are pre-formed into a general configuration that is easy to fabricate or, in selected examples, the implants are preformed to a generalized configuration that may or may not conform to a specifically targeted bone structure. Often the bone structure must modified to conform to the generalized implant device.

In selected cases, some implants can be shaped by the surgeon immediately prior to surgery or during surgery. One example of a deformable bone plate is described in U.S. Patent No. 5,868,746, issued to Sarver et al. This patent discloses an osteosynthesis plate that is relatively rigid at a first temperature, and deformable at a second temperature. The plate can be deformed and then subsequently returned to its original configuration by heating the plate to a second temperature. However, this implant requires a surgeon to spend significant amounts of time to shape and repeatedly reshape or re-form the implant to conform to the anatomical structure of bone. This is a very difficult and time-consuming task, which can lead to complications during the operation. It would be preferable to provide an implant that can be preformed to the desired configuration prior to anesthetizing the patient or,

alternatively, is self-conforming to the selected or targeted bone tissue after implantation. However, the implant must still provide sufficient strength to support the load exerted by the bone structure and be able to promote fusion or fixation of bone fragments.

Thus, in light of the above-described problems, there continues to be a need for advancements in the relevant field, including improved orthopedic implants for treatment of muscular-skeletal diseases and defects. The present invention is such an advancement and provides a wide variety of additional benefits and advantages.

SUMMARY OF THE INVENTION

The present invention relates to self- conforming implants, the manufacture and use thereof. Various aspects of the invention are novel, nonobvious, and provide various advantages. While the actual nature of the invention covered herein can only be determined with reference to the claims appended hereto, certain forms and features, which are characteristic of the preferred embodiments disclosed herein, are described briefly as follows.

In general, this invention provides a self-forming implant for treatment of muscular skeletal diseases and general orthopedic defects. The implant is formed of a shape memory polymer (SMP) and fabricated into a pre-selected configuration. Fabrication of the implant using a shape memory polymeric material imparts novel and particularly advantageous characteristics to the implant. In a preferred embodiment, the implant fabricated from a SMP can be molded into a desired configuration. However, when the implant is heated above a deformation temperature (T_d)-- which is usually equivalent to the glass transition temperature (T_g) of the polymeric material, the SMP becomes elastic. The implant can then be deformed to a wide variety of configurations by applying pressure or forcing it into a mold. Cooling the deformed implant below T_d fixes it in its deformed state. Thereafter the deformed implant retains the deformed configuration until it is heated above T_d. When the implant is reheated above T_d, the SMP again becomes elastic; and in the absence of any applied pressure, the implant automatically reverts to its original configuration. This process can be repeated any number of times without detrimental effect on the SMP or the implant itself.

In one form, the present invention provides a fabricated implant molded to a desired shape and/or size. The implant comprises a body composed of a polymeric material that exhibits a shape memory effect above a deformation temperature. Above the deformation temperature, the body can be deformed to a first configuration. Preferably, the first configuration provides a reduced external volume or cross-sectional area. Cooling the deformed implant to a temperature below the deformation temperature effectively freezes the deformed implant in the first

configuration. The deformed implant can then maintain the first configuration until it is desired to cause the implant to revert to its original, molded configuration. It should be understood that the implant can be deformed/conformed to a desired configuration and allowed to recover to its original configuration at any time--either before or after implantation into the disc space. In one form, the deformed implant is smaller than the original implant, and the deformed implant can be more readily inserted into a bone cavity or other defect. In a particularly preferred form, the implanted, deformed implant is heated above its deformation temperature and reverts to its original configuration or a second configuration substantially equivalent to its original configuration. The resulting implanted implant can essentially fill the targeted cavity, defect or conform to the anatomical configuration of the bone structure.

In one form, the present invention provides an orthopedic implant for a bone structure. The implant comprises a deformable body formed of a shape memory polymeric material. The body is provided in a first configuration and capable of deforming to a second configuration upon application of selected stimuli to conform to a portion of the bone structure.

In preferred embodiments, the implant is provided to exhibit a compression modulus sufficient to withstand the biomechanical forces exerted by adjacent bone or neighboring muscular structures without significant deformation. Additionally, the implant can be provided with cavities, which serve as depots for biological material such as an osteogenic material to promote bone fusion. In other preferred embodiments, the implant is deformable at a deformation temperature selected to be at body temperature and below. In yet other embodiments, the implant can be deformed to a second configuration that exhibits an expanded cross-sectional area compared to the first configuration.

In another form, the present invention provides an orthopedic implant for two or more adjacent bone portions. The implant comprises a body formed of a material comprising a shape memory polymer. The body is provided in a first configuration and adapted to bear against adjacent bone portions, wherein the body deforms upon

application of selected stimuli to a second configuration to apply a force to the adjacent bone portions.

Preferably, the implant exhibits a tensile strength sufficient to join adjacent bone structures or fragments. In this form, the implant can serve as a connective member, i.e., to replace or augment connective tissue, such as ligaments and tendons. In one embodiment, this implant is selected to be deformable at a deformation temperature selected to be less than or equal to body temperature. In yet other embodiments, the implant can be provided in a first configuration; and upon application of selected stimuli, the implant can deform to a second configuration that exhibits a retracted or a reduced cross-sectional area. The retracted state can join a bone structure and replace targeted muscle tissue.

In another form, the present invention provides a spacer for insertion into a spine. The spacer formed of a material including a shape memory polymer and is movable between a first configuration and a second configuration by action of the shape memory polymer.

In another form, the present invention provides a method of orthopedic treatment of a bone defect, the method comprising: selecting an orthopedic implant comprising a deformable body provided in a first configuration and formed of a shape memory polymeric material; contacting the implant to the bone defect; and stimulating the implant to deform the body to a second configuration.

In yet another form, the present invention provides a method of preparing a self-forming orthopedic implant. The method comprises: fabricating an implant from a shape memory polymeric material, wherein the implant comprises a deformable body provided in an original configuration; deforming the body to a first configuration; and stimulating the body to induce the body to revert to the original configuration or a second configuration substantially equivalent thereto.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of one embodiment of a deformable implant according to the present invention.

FIG. 2 is a perspective view of one embodiment of a deformed implant derived from the implant illustrated in FIG. 1.

FIG. 3 is a perspective view of the bi-laterial placement of a pair of deformable implants between adjacent vertebrae in accordance with one embodiment of the present invention.

FIG. 4 is a perspective view of one embodiment of a C-shaped, deformable implant according to this invention.

FIG. 5 is a perspective view of one embodiment of a spiral wound deformable implant for use in the present invention.

FIG. 6 is a perspective view of one embodiment of a deformed implant derived from the implant of FIG. 5.

FIG. 7 is a perspective view of an alternative embodiment of a deformed implant derived from the implant of FIG. 5.

FIG. 8 is a perspective view of a deformed bone plate derived from the implant of FIG. 4 for use in the present invention.

FIG. 9 is a perspective view of one embodiment of a deformable bone plate for use in this invention.

FIG. 10 is a perspective view one embodiment of a deformed bone plate derived from bone plate of FIG. 9.

FIG. 11 is a perspective view of the deformed implant of FIG. 10 secured to bone tissue.

FIG. 12 is a perspective view of the deformed bone plate derived from the implant of FIG. 10 secured to three vertebral bodies.

DETAILED DESCRIPTION OF THE INVENTION

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated herein and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended. Any alterations and further modifications in the described processes, systems or devices, and any further applications of the principles of the invention as described herein, are contemplated as would normally occur to one skilled in the art to which the invention relates.

In general, this invention provides a self-forming implant for use in treating orthopedic defects. By use of the term orthopedic defect, it is intended to also include muscular-skeletal defects in general. The implant is formed of a shape memory polymeric material and fabricated into a pre-selected, original configuration. In one embodiment, the implant can then be heated to a deformation temperature and deformed in to a first configuration that facilitates insertion. Additionally the implant can be reheated to the deformation temperature either before of after implantation. Preferably the implant is heated to the deformation temperature after implantation. The reheated implant recovers its original configuration or a second substantially equivalent configuration. In preferred embodiments, the second configuration conforms to the defect or bone structure to be treated. Alternatively, the implant can be heated to the deformation temperature and reformed to yet another configuration. The heating and reforming process can be repeated until a desired configuration is achieved. In one form, the deformed implant in the first configuration has a reduced cross-sectional profile that permits it to be readily surgically implanted into a patient through a small incision. The deformed implant can be surgically implanted in variety of defects, for example a void in bone tissue, a cavity between adjacent bone structures, or overlying a bone fracture.

In alternative forms, the implant can be provided to connect adjacent bone structures and/or replace tendons and ligaments. The implant can be provided in a

pre-selected configuration, preferably as a bone plate, either flat or curved. The bone plate can then be deformed to facilitate attachment to the selected bone or muscle tissue. Application of selected stimuli to the deformed bone plate initiates self-deformation to its originally pre-selected configuration. In preferred forms, the original pre-selected configuration compresses the adjacent bone structures into alignment and/or contact with each other. Thus, the implant can be used to facilitate fixation of bone fragments, reconnect adjacent structures, or replace tendons between adjacent bone structures, as well as attachment of tendons or ligaments to bone structures.

FIG. 1 is an illustration of one embodiment of an implant 10 fabricated in an original configuration for use in the present invention. Implant 10 includes circular body 12 which is formed from a shape memory polymeric material. Body 12 further defines a vertical axis 11 extending therethrough. Body 12 includes a peripheral wall 18 having an upper, first surface 14 and an opposite, second surface 16. In the illustrated embodiment first surface 14 and second surface 16 are adapted to bear against opposing bone tissue. While the first and second surfaces 14 and 16 are illustrated as substantially circular, planer surfaces, one or both of these surfaces can be provided in alternative forms. For example, the surface need not be planar or circular. In this respect, implant 10 is provided as a generalized construct of a self-forming implant according to this invention. In use, an implant is fabricated in an original configuration to conform to a defect or cavity in bone tissue or to be inserted between adjacent bone structures. Preferably, the alternative forms conform to the anatomical configuration of the opposing bone structure into which the implant is inserted. First surface 14 and second surface 16 are provided in a wide variety of widths, measured transverse to vertical axis 11 and illustrated by reference line 15. Preferably, the widths for surfaces 14 and 16 are selected to provide suitable bearing surfaces to maintain a desired separation between the opposing bone tissue in the cavity or defect. (See, for example, Fig. 3.)

Peripheral wall 18 also includes a first end 19, an opposite second end 21. Since peripheral wall is circular, first end 19 and second end 21 are positioned

adjacent to each other with an alignment portion 23. In the illustrated embodiment, alignment portion 23 includes tab 25 on first end surface 19. Tab 25 is received within a recess 27 located in second end 21. It should be understood that a variety of alignment structures could be included in peripheral wall 18, for example, groove, slots, dovetails and the like. Additionally, it is not necessary that the first end surface 19 contact surface 21 (see, for example, FIG. 4). Further, as will be seen in alternative embodiments described below, the peripheral wall 18 can include various wall portions, each having its own surface features.

Peripheral wall 18 is illustrated as a substantially curved wall portion concentric about vertical axis 11 and defining cavity 20. First surface 14 defines an opening 30 providing a passageway into cavity 20. Similarly second surface 16 defines opening 32 and a passageway into cavity 20. Cavity 20 can serve as a depot for biologically active material, preferably tissue inducing growth factors, for example, antibiotic materials, an osteogenic material to promote bone fusion between the adjacent bone structures, and other tissue growth factors, for example: bone morphogenetic proteins (BMPs), LIM mineralization proteins (LMPs), including LMP-1, growth differentiation factors (GDF), cartilage-derived morphogenic proteins (CDMP) and other growth factors such as epidermal growth factors, platelet-derived growth factors, insulin-like growth factors, fibroblast growth factors and transforming growth factors, including TGF-β and TGF-α, and combinations thereof. While it is understood that the size/diameter of each of cavity 20, and openings 30 and 32 can vary, depending on the targeted bone tissue, preferably cavity 20 is provided in a size sufficient to provide a suitable amount of the biologically active material to opposing bone structures in a medically expedient fashion. Peripheral wall 18 can also include a variety of openings extending therethrough, providing access to internal cavity 20.

Preferably implant 10 is provided with a compression modulus substantially equivalent to that of cortical bone tissue. Thus, pre-formed implant 10 can be inserted between adjacent bone structure in a defect to provide suitable biomechanical support for adjacent bone tissue--yet without stress shielding the bone. In one preferred embodiment, implant 10 is inserted in the disc space

between adjacent vertebrae. Therefore, body 12 is provided to withstand the biomechanical forces exerted by the spine during normal patient activity. In alternative forms, implant 10 can be inserted into any of the load-bearing supporting bones. Therefore, it is desirable that the implant 10 be formed of a shape memory polymeric material having suitable compressive strength to withstand the load exerted by the load-bearing bones. This shape memory polymeric material can also be fashioned to have the same tensile properties of connective tissues such as ligaments, cartilage and tendons with adequate strength to support the *in vivo* physiological loads, and thus the implant can be used for replacement of such structures.

FIG. 2 illustrates a deformed implant 40 derived by heating implant 10 above a pre-selected deformation temperature and applying a force to separate first end 19 from second end 21. Implant 40 includes an elongated central portion 42 resembling a substantially planar sheet or plate 44. Elongate central portion 42 defines a longitudinal axis 45 and terminates with first end 46 in opposite second end 48. First end 46 includes a tab 49, while second end includes slot 50 adapted to receive tab 49 when central portion 42 is bent to position first end 46 adjacent second end 48.

In one form, implant 40 when viewed along longitudinal axis 45 presents a cross-sectional profile that is substantially smaller than the cross sectional profile of implant 10 viewed orthogonal to vertical axis 11. Therefore while central portion 42 may have substantially the same overall dimensions as peripheral wall 18, implant 40 can be inserted into a much small incision and through a small passageway into a targeted bone cavity.

In one preferred use, implant 10 is manufactured to a desired, original configuration having a pre-selected size using a shape memory polymer. Thereafter, implant 10 is heated to a temperature equal to or greater than its deformation temperature and deformed into a second configuration, such as, implant 40. Implant 40 is inserted through a small incision into a bone defect or between adjacent bone structures. After implant 40 is positioned as desired by the surgeon, the implant is heated to its deformation temperature again. In the absence

of external pressure, implant 40 recovers to its original configuration exemplified by implant 10. However, in a particularly preferred embodiment, implant 10 is selected to occupy a space slightly larger than the interior area defined by the bone defect or between the adjacent bone structures. Above the deformation temperature the thermodynamic forces will drive a deformed implant to revert to its original configuration. However, since the shape memory polymer is elastic or super elastic above its deformation temperature, the bony surfaces defining the defect or area between the adjacent bone structures will constrain and/or conform the resulting implant into a second, smaller configuration. It is desirable that the second configuration be substantially equivalent to the original configuration to avoid excessive strain on the deformed implant and/or neighboring tissue. Thus, the implant, in its second configuration, automatically conforms to the anatomical structure of the defect, and the surgeon does not spend significant amounts of time shaping and repeatedly reshaping the implant to conform to the anatomical structure of bone.

The deformation temperature can be pre-selected by modifying or selecting a specific shape memory polymer as is described more fully below. In preferred embodiments, the deformation temperature is selected to be above body temperature, but less than the temperature at which adjacent tissue (and organs) can become substantially traumatized and/or damaged. In preferred embodiments, the deformation temperature is selected to be above about 38° C and below about 100° C; more preferably, the deformation temperature is selected to be between about 38° C and about 65° C; still yet more preferably, the deformation temperature is selected to be between about 38° C and about 45° C.

While the foregoing discussion has focused on selecting an SMP that exhibits an elasticity or super elasticity above a selected temperature. It should be understood that other polymers can be selected for this invention that respond to other stimuli, such as light or radiation, pH changes, and/or chemical/solvent additives. When the selected stimuli is applied to the polymer, the polymer responds, in turn, by a physical change--preferably to revert to its original molded configuration.

FIG. 3 illustrates the bi-level placement of a pair of expanded implant 60A and 60B in a disc space 61 between adjacent vertebrae 62 and 64 in accordance with the present invention. Examples of intervertebral implants are discussed in co-pending U.S. Patent Application Serial No. 09/696,715, entitled, "Laterally Expanding Intervertebral Fusion Device," filed on October 25, 2000 (Attorney Docket No. 4002-2507) and U.S. Patent Application Serial No. 09/696,146, entitled, "Vertically Expanding Intervertebral Fusion Device," filed on October 25, 2000 (Attorney Docket No. 4002-2506). of which the entire disclosures are incorporated herein by reference. Implants 60A and 60B are derived from implant 10 of FIG. 1. In a preferred embodiment, implant 10 is sized to be larger than internal dimensions of disc space 61. Implant 10 is heated above its deformation temperature and compressed in to a first conformation having a reduced external volume. After cooling, the deformed implant is inserted into a targeted disc space and then reheated. The resulting implants 60A and 60B are illustrated in FIG. 3. Implant 60A will be discussed in more detail with the understanding that the same discussion applies equally to implant 60B. Implant 60A includes an exterior surface 66 defining cylindrical body 68.

In a preferred embodiment, expanded implant 60A reverts to the substantially equivalent configuration of that exhibited by the original implant 10. However, it will be understood that because of boundary constraints within the disc space 61, implant 60A may not expand to the height and/or width of the original configuration. Instead, implant 60A may expands to a height and/or width until exterior surface 66 bearings against adjacent bone tissue such as the endplates 70 and 72 of the respective vertebrae 62 and 64. When implant 60A is maintained at the deformation temperature or above, the SMP material exhibits an elasticity or super elasticity, and it can be compressed by any number of forces. The compressive force exerted by the opposing endplates of vertebrae 62 and 64 can compress upon the respective exterior surface 66 to conform implant body 68 to the existing anatomical structure of the opposing endplates. Thus, while it may be observed that implant 60A expands in a direction laterally and/or vertically within the intervertebral space 61, it will also be understood by those skilled in the art that

compression forces exerted by the adjacent vertebrae may at the same time compress body 68 to have a reduced height and/or lateral dimension compared to the original implant 10. Typically during surgery, the vertebrae are distracted to increase the disc space height. The amount of distraction can be varied and controlled by the surgeon. Thus, implant 60A conforms to the internal configuration of disc space 61. This provides an optimal fit in the disc space, decreases the potential for retropulsion of the implanted implant, and when the implant is packed with osteogenic material, and maintains the osteogenic material in intimate contact with the cancellous bone tissue.

Once implant 60A is cooled below the deformation temperature, implant 60A is then frozen into a substantially rigid form that does not further decompress or expand when stressed by the load exerted by the spinal column. In one form the SMP material is selected to exhibit a compressive modulus similar to that of cancellous bone tissue. Preferably the SMP material selected for implant 60A below its deformation temperature exhibits a compression modulus between about 2 MPa and about 30 MPa below the deformation temperature; more preferably between about 8 MPa and about 15 Mpa. As discussed more fully below, the shape memory polymeric material can be selected from a wide variety of known materials, and it can include both biodegradable and non-biodegradable materials.

While the foregoing discussion has been applied to a pair of identical implants 60A and 60B, use of two or more unique implants within the same intervertebral space is also included with this invention. For certain orthopedic treatments, it may be desirable to use two different, unique implants. In one embodiment, the two implants can be mirror images of each other. Accordingly, each of the implants can be provided in a configuration that matingly bears against only a portion of the opposing endplates. For example, a single implant may be used to bear against a portion of the endplate beginning at the midline of the endplate and extending laterally toward the lateral facet. Alternatively, because of a bone defect, tumor, or diseased bone tissue, the surgeon may desire to combine in a selected vertebral space differently sized implants or even implants with a different configuration.

FIG. 4 illustrates yet another embodiment of an implant 100 for use in the present invention. Implant 100 is provided as substantially described for implant 10 and includes body 102 defining an interior region 104. As can be seen from the illustration, implant body 102 does not provide a substantially enclosed interior region 104. Rather, implant body 102 is formed to include a first end 106 and a second end 108 that do not contact each other. First end 106 and second end 108 define a passageway 110 into interior region 104. Thus, body 102 can be described as a substantial "C" implant. Alternative configurations for implant 100 include "J" configurations and "U" configurations. In use, implant 100 can be inserted either singly, or in combination with other implants. In preferred embodiments, a pair of implants 100 are inserted bi-laterally such that the opening 104 between first end 106 and second end 108 are opposite each other to form an enlarged interior region for receipt of an osteogenic material.

FIG. 5 illustrates one example of an implant 140 that a spirally wound sidewall 142 having an exterior surface 144 and an interior surface 145. Implant 140 also includes an upper surface 148 and an opposite, lower surface 150. In a preferred use, upper surface 148 and lower surface 150 are adapted to bear against the opposing structures of bone tissue.

FIG. 6 illustrates one embodiment of a deformed implant 180 derived from implant 140 for use in the present invention. Deformed implant 180 includes an elongated body 182 defining longitudinal axis 184. Body 182 is provided as a substantially elongate plate 185 having a first bearing surface 186 and an opposite second bearing surface 188. In the illustrated embodiment, an osteogenic material 190 is deposited on first bearing surface 186. Upon application of selected stimuli, for example, heating above a deformation temperature, implant 180 self-reverts to its original configuration or a substantially equivalent second configuration.

FIG. 7 depicts a spirally wound implant 200 derived from deformed implant 180. Implant 200 includes a spirally wound body 201 defining a vertical axis 203. Implant further includes a first surface 202 an opposite second surface 204 and osteogenic material 206 entrapped between first surface 202 and second surface 204. Body 201 also includes a first end 208 positioned to lie substantially

orthogonal first surface 202 and an opposite second end 210. Implant 200 can be inserted into a void between bone tissue such that first end 208 and second end 210 are provided to bear against bony tissue in the void. When thus engaged, first end 208 and second end 210 maintain a source of osteogenic material 206 in intimate contact with the opposing bone tissue surfaces.

In another form, the present invention provides an implant for orthopedic and/or muscular-skeletal disorders that exerts a compressive force on bone tissue and adjacent bone structures and/or fixates bone fragments. In preferred embodiments the implants are applied to the surface of the bone rather than in between adjacent bone structure or into a bone cavity. In this form, the deformation temperature of the shape memory polymer can be selected to be either above or below normal body depending upon the desired use and course of treatment.

Implants 10, 100 and 180 can be used to apply a compressive force or stress to adjacent or underlying bone tissue such as for fixation of bone fragments or joining fractured bone tissue. Referring specifically to C-shaped implant 100 of FIG. 4, body 102 includes an interior surface 220 and an opposite exterior surface 222. Referring additionally to FIG. 8, in one embodiment, implant 100 can be applied to a bone fracture 230 in bone tissue 232. In this application, it is preferably, but not required that implant 100 be sized to be smaller than the underlying bone tissue 232. Preferably implant 100 has a radius defined by the curvature of interior surface 222 that is smaller than the average radius of the external surface 233 proximal to fracture 230 in bone tissue 232. Implant 100 can be provided in a wide variety of sizes and have a length and width sufficient to adequately cover fracture 230 in the underlying bone tissue 232. Alternatively, implant 100 can be provided as a substantially uniform size or as one of a series of implants provided in a range of uniformly increasing sizes. Since body 102 of implant 100 is formed of a polymeric material, a surgeon can readily cut it to a desired width and height during or immediately prior to surgery.

FIG. 9 illustrates one embodiment of an implant 250 for use as a compressive implant in the present invention. Implant 250 is illustrated as a

substantially elongate plate 252 defining the longitudinal axis 254. Plate 252 includes a first bearing surface 256 and an opposite second surface 258. A peripheral sidewall 260 is positioned between first bearing surface 256 and opposite second surface 258. It should be understood that implant 250 can be provided in a variety of sizes and configurations. In alternative embodiments, implant 250 need not be provided as a substantially planar or flat plate. (See, for example, FIG. 12). Implant 250 is provided to have a length L_1, measured along axis 254 and illustrated by reference line 261. Similarly, implant 250 has a width W_1 measured transverse to longitudinal axis 254. Length L_1 and width W_1 are selected to allow bearing surface 256 to bridge a bone defect and to ensure secure engagement of plate 252 to the underlying bone tissue. Furthermore, regardless of the originally dimensions of implant 250, since the implant is formed of a polymeric material, its dimension and shape can be readily modified immediately prior to or during surgery by the surgeon. This modification can include cutting the implant 250 to the desired size and shape to cover the exact anatomical configuration of the bone tissue to be repaired and heating implant 250 to a deformation temperature to mold it into desired shape. Implant 250 can also include a variety of openings 264 formed to receive fasteners such as bone screws, staples, pins and sutures.

In one preferred embodiment, implant 250 formed from a shape memory polymeric material having a deformation temperature equal to or below normal body temperature--preferably between about 38° C and ambient room temperature; more preferably between about 37°C and about 15° C. Referring additionally to FIG. 10, in one use, before implant 250 is implanted, it is maintained at its pre-selected deformation temperature and deformed, preferably by stretching either along longitudinal axis 254 or in a direction oblique to longitudinal axis or both. Alternatively, implant can be deformed in any other desired configuration to facilitate implantation of the implant in a patent. Deformed implant 280 depicted in FIG. 10 illustrates but one embodiment of a deformed implant derived from stretching implant 250 along its longitudinal axis. Deformed implant 280 includes a body 282 having a longitudinal length L_2 measured along axis 284 illustrated by

reference line 286 that is greater than L_1 for implant 250. For example, in certain embodiments L_2 can be provided to be at least about 20% longer than length L_1. More preferably, length L_2 can be provided to be greater than about 40% longer than length L_1 of implant 250.

Referring additionally to FIG. 11, there is provided an illustration of the application deformed implant 250 to damaged bone tissue 300. The separated bone or fragmented bone 302 (shown in partial section) can be loosely joined together by the surgeon during the operation. Initially deformed, implant 280 from FIG 10 can be secured to a selected bone portion or fragment with means commonly used in orthopedic surgery, for example using fasteners, i.e., bone screws, pins, sutures and bone adhesives inserted through one or more openings 288. The selection of the appropriate means and location of attachment can be made by the surgeon during the operation after considering the available bone tissue, the health of the underlying bone tissue, and the general anatomical configuration of the healthy bone tissue. Since implant 280 is formed of a polymer, additional holes for fasteners can readily be provided during surgery. Additional fasteners can secured to bone tissue on the opposite side of the fracture or into other bone fragments. After implant 280 has been securely fastened to the bone tissue covering the cavity or fragmented bone tissue, the implant can be subjected to a selected stimuli, for example, heating above a deformation temperature T_d, to induce the implant to recover its original configuration and size as illustrated by implant 250 in FIG. 11.

It will be understood by those skilled in the art that the thermodynamic driving force to return deformed implant 280 to its original configuration illustrated by implant 250 will exert a force on the bone fragments, fracture or connective tissue (i.e., tendons, ligaments and cartilage), causing them into close or substantial bearing relationship to each other. This serves to facilitate repair of the bone fragments and connective tissue. Additionally the implant can serve as to augment connective tissue or as a connective tissue replacement for the bone structures. In this form the implant can be either biodegradable or non-biodegradable. When the implant is biodegradable, it is preferable that the implant

include tissue promoting growth factors either deposited into a cavity, coated on one or more of the surfaces of the implant, or absorbed within the polymeric matrix.

In an alternative embodiment, the deformation temperature of the shape memory polymeric material can be selected to be above normal body temperature as described above for implants 10, 100 and 140. Application of thermal energy to the secured deformed implant serves to fixate the bone fragments and/or close the fracture in bone tissue 300. This embodiment may find advantageous use when the bone defect requires additional compressive force to coalesce the bone fragments or fracture. Cooling the implant below it deformation temperature effective freezes it in the secured, compressed conformation to facilitate fixation of the bone fragments and ultimately fusion of the bone tissue.

FIG. 12 illustrates a secured implant 330 spanning to three adjacent vertebrae. In use, implant 330 can be used to attach adjacent lumbar vertebrae and either re-attach, strengthen, or replace a damaged anterior longitudinal ligament (ALL). The implanted bone plate can improve stability in extension of a patient's spine after surgery--yet still maintain desired disc height between the co-joined vertebra. In this embodiment, implant 330 can be deformed prior to insertion into the patient or attachment to the selected vertebrae. Preferably implant deformed by stretching a deformable plate along its longitudinal axis as described for implant 250 and 280. Thereafter, the deformed implant can be attached to the desired vertebrae 340, 342 and 344. If implant 330 is formed of a shape memory polymeric material that has a deformation temperature equal to or below normal body temperature, the surgeon preferably should attach the implant in its deformed configuration to vertebrae, 340, 342 and 344 before implant 320 absorbs sufficient energy from the patient and begins to recover its original configuration. Once the secured implant adsorbs sufficient energy from the patient or is subsequently heated above its deformation temperature, the shape memory polymeric material becomes elastic. The internal thermodynamic forces in the polymer induce a stress on the shaped implant to recover to its original configuration. This strain can be transferred to the attached vertebrae 340, 342 and 344 forcing them to assume a

desired disc space height and/or orientation. It is to be understood that because of the constraints placed upon the vertebrae, implant 330 may not fully retain the configuration, length, and width of the pre-formed implant 320. Further, since the deformation temperature is selected to be equal to or below body temperature, implant 330 remains in an elastic or super elastic state and continues to provide tension to the attached vertebrae and urges them into a desired alignment during the plate's effective lifetime. While FIG. 12 depicts attachment of implant 330 to vertebral bodies, it is understood that the implant can be provided to attach/connect any bone structure. In alternate forms, the implant 320 can replace or augment any connective tissue, such as ligaments, tendons, and/or cartilage. Thus, the SMP material can have properties to mimic the connective tissue. In particular, the SMP material is selected to exhibit tinsel strength to connect adjacent bone structures.

Each of the implants discussed above can be formed of a shaped memory polymeric material. The shaped memory polymeric material can be selected from a wide variety of polymers, including biodegradable and non-biodegradable polymers. In preferred embodiments, the shape memory polymeric material is formed from oligomers, homopolymers, copolymers, and polymer blends that include polymerized monomers derived from l, d, or d/l lactide (lactic acid); glycolide (glycolic acid); ethers; olefins, such as ethylene, propylene, butene-1, pentene-1, hexene-1, 4-methylpentene-1, styrene, norbornene and the like; butadiene; polyfunctional monomers such as acrylate, methacrylate, methyl methacrylate; esters, for example, caprolactone, and mixtures of these monomeric repeating units.

Use of the term copolymers is intended to include within the scope of the invention polymers formed of two or more unique monomeric repeating units. Such copolymers can include random copolymers, graft copolymers, block copolymers, radial block, diblock, triblock copolymers, alternating copolymers, and periodic copolymers. Use of the term polymer blend is intended to include polymer alloys, semi-interpenetrating polymer networks (SIPN) and interpenetrating polymer networks (IPN).

Preferred shape-memory molded implants of this invention are fabricated to include homopolymers, copolymers, polymer blends, and oligomers of d, l, d/l, polylactide; polyglycolide, poly(lactide-co-glycolide), poly(β-hydroxy butyrate); poly(β-hydroxy butyrate-co-hydroxyvalerate), poly(trimethylene carbonate) polyurethane, poly(ethylene-co-vinyl acetate) (EVA), poly(ethylene-co-propylene) (EPR), poly(ethylene-co-propylene-co-diene) a ter-polymer (EPDM), poly(ε-caprolactone), poly imino carbonates polyanhydrides, copolymers of ethylene and propylene and/or other α-olefins: or copolymers of these α-olefins. Among them, various types of polyethylene, such as low-density polyethylene, linear low-density polyethylene, medium-density polyethylene and high-density polyethylene, and polypropylene are preferable.

Preferred polymers include biodegradable homopolymers of lactide or glycolide or copolymers thereof. Exemplary polymers are described in U.S. Patent No. 4,950,258, the entire disclosure of which is incorporated by reference herein. When copolymers of lactide and glycolide are used to form the molded products, the copolymers preferably consist essentially of a composition of 90-10 mol.% lactide and 10-90 mol.% glycolide, and most preferably consist essentially of 80-20 mol.% lactide and 20-80 mol.% of glycolide. Within these specified ranges, the copolymers exhibit desirable deformation characteristics. For example, the copolymers are more pliable and readily deformable at lower temperatures when their mole ratio of lactide and glycolide approximates to 1:1. Generally, the less crystalline phases in the SMP material, the lower the deformation temperature.

The polymer composition of the present invention may further contain thermoplastic resins and/or thermoplastic elastomers to improve its stiffness, moldability and formability. In addition, the shape-memory molded implant may additionally include additives such as coloring agents, stabilizers, fillers, and the like, in an amount such as will not alter the desired shape-memory effect, biocompatibility and/or biodegradability properties of the molded implants.

The polymer is characterized in that it will attempt to assume its memory condition by activation of a polymer transition. Activation can occur by adsorption of heat by the polymer, adsorption of liquid by the polymer, or a change in pH in

the liquid in contact with the polymer. The polymer is formulated to be responsive to adsorption of a liquid by incorporating in the polymer a hydrophilic material, such an n-vinyl pyrrolidone. Incorporation of a material such as methacrylic acid or acrylic acid into the polymer results in a polymer having a transition that is sensitive to pH. The polymer transition may be a thermally activated transition, where upon adsorption of heat the polymer undergoes a glass transition or a crystalline melting point.

It is also considered to be within the scope of the present invention to provide intervertebral implants that are formed of a laminate material that comprises one or more layers of a shape memory polymeric material. For example, molded implant 10 can be provided with an upper surface 12 that includes an exterior layer of a shape memory polymeric material. Similarly, lower surface 14 can also be provided with a laminated layer of a shape memory polymer. The material used to form the sidewall 16 can be formed of any conventional biocompatible polymeric material. In preferred forms, the peripheral sidewall is formed of a biodegradable polymeric material as has been described above. When thus provided, the laminated implant can be provided to include different layes with varying compressive strengths depending upon the desired deformation of the implant at a constant temperature. For example, a laminated structure where the external layers are formed of a shaped memory polymeric material can have a compressive modulus that is significantly less than the polymeric material used to form the intermediate layer for the peripheral sidewall 114. This provides distinct advantages for implants by use of the present invention. For example, implants can have increasing compressive strength to allow greater flexibility of the spine. Alternatively, the laminated structure can provide varying rates of biodegradability in the body. For example, the external laminated layers can be provided in a form having less crystallinity than the intermediate layer for the peripheral sidewall. When polymers such as biodegradable polymers are provided with less crystallinity, they degrade at a much faster rate than polymers that have greater degrees of crystallinity. Polymers with less degree of crystallinity can be prepared by providing copolymers of lactic

acid and glycolic acid. Increasing the amount of glycolic acid or varying the amount of d to l isomers of lactic acid in the polymer decreases its crystallinity and therefore increases its rate of degradation.

As mentioned above, the implant can be deformed when heated above its deformation temperature. The deformation temperature (T_d) in most situations will be substantially equal to the glass transition temperature (T_g). When heated above its deformation temperature, the polymeric material exhibits an elasticity or super elasticity that allows it to be molded into a variety of shapes. For example, for the present invention, the molded implant can be heated to a temperature between about 40° and 100° C. Application of a compressive force to deform the implant into a deformed configuration having a reduced cross-sectional profile can then be applied. Preferred examples of the compressive force needed to deform the implant in a range between about 18 KPa and about 900 KPa . The deformed implant can then be cooled below the T_d, which effectively freezes the deformed implant into its deformed configuration. The deformed implant can be used immediately, or the deformed implant can be stored and/or shipped for use at a later time. Obvious prior to use the deformed implant should be sterilized, preferably using chemical or radiation sterilization techniques.

During surgery, the disc space is prepared to receive the deformed implant. The surgical techniques for partial or full discectomy are commonly known by surgeons skilled in the art. The deformed implant can be inserted from a variety of directions, including posteriorly, anteriorly, or posterior laterally.

After implantation of the deformed implant into the prepared disc space, the deformed implant is then heated above its glass transition temperature. This can be accomplished by a variety of techniques and instrumentation. For example, the deformed implant can be flushed with warm saline solution, which can then be suctioned out of the patient. Obviously, it is preferable that the warm saline solution be kept at a low enough temperature that it does not traumatize or damage the adjacent tissue. Alternatively, when the implant includes an opening into its sidewall, the osteogenic material may be heated sufficiently high and thereafter injected into the opening into the peripheral sidewall of the deformed implant.

This can be done in addition or instead of flushing the disc space with warm, sterile saline solution.

In yet another embodiment, a heating tool or other suitable electronic device can be used to heat the implanted deformed implant without warming and traumatizing the adjacent body tissue. Any suitable heat generating apparatus can be used to heat the SMP material such as a hot air gun, a small welding or soldering gun, or an electrocautery tip. Also usable are lasers, which are commonly provided in operating rooms. Lasers are especially desirable because they are precise and controlled in their application, can generate sufficient heat very quickly, and cause less thermal necrosis because there is less misdirected heat. The heating operation can be performed during surgery, in the body. Still other embodiments include the use of ultra sonic devices, light and or other electromagnetic radiation generating devices.

After the deformed implant has been heated above its deformation temperature, the deformed implant automatically undergoes a transition in which it reverts back to its originally molded configuration. However, as has been discussed above, due to spatial constraints within the disc space, the deformed implant may not be able to obtain the full height (H_I) that was originally provided in the originally molded implant.

When the expanded implant has been expanded to the desired height, the surgeon can then remove the heat source, thus allowing the expanded implant to cool down below the deformation temperature and freeze it into its second or expanded confirmation. The implants will cool to below their deformation temperature relatively short time. After the implants are frozen into their expanded configuration, the surgeon can reduce any distraction that has been applied to the adjacent vertebral bodies. In this expanded confirmation, the implanted implant has sufficient compressive modulus to withstand the biomechanical load exerted by the spinal column.

To further increase the compressive modulus of the implant, the polymeric material used to form the implant can include a wide variety of additives such as fillers; binders; reinforcement phases; such as fibers, for example, glass fiber and

carbon fibers and the like; aggregates, for example, ceramic particles or bone derived particles; and platelets.

The spacer can be fabricated by a wide variety of techniques, including injection molding, extrusion molding, vacuum molding, blow molding, and transfer molding. The laminated structures can be fabricated using techniques known in the art including coextrusion, overmolding of the adjacent layers and using biocompatible adhesives to form the laminated structures. Curing the polymeric material or propagating crosslinks between the polymer chains imprints the original molded configuration to the implant body. It will be understood that curing the polymer can include heat, solvent, or pH changes. Additionally, a crosslinkable additive can be included to a polymer or pre-polymeric material to provide the crosslinkable additive that can be induced to crosslink to provide the SMP material.

The term osteogenic material used here means virtually any osteo-conductive or osteo-inductive material that promotes bone growth or healing including natural, synthetic and recombinant proteins, hormones and the like. The osteogenic materials used in this invention preferably comprise a therapeutically effective amount of a bone inductive factor such as a bone morphogenic protein in a pharmaceutically acceptable carrier. Examples of factors include recombinant human bone morphogenic proteins (rhBMPs) rhBMP-2, rhBMP-4 and heterodimers thereof. However, any bone morphogenic protein is contemplated including bone morphogenic proteins designated as BMP-1 through BMP-13, which are available from Genetics Institute, Inc., Cambridge, Mass. All osteo-inductive factors are contemplated whether obtained as above or isolated from bone.

The osteogenic material can include a demineralized bone matrix and optionally a carrier, such as a gelatin substance. The demineralized bone matrix can be provided in the form of a powder, paste or gel. When provided as a powder, the osteogenic material can be reconstituted with sterile water, saline, glycerin or other physiological solutions. The reconstituted material is molded about the implant assembly. An osteogenic material can be applied to the

intervertebral implant by the surgeon during surgery or the implant may be supplied with the composition pre-applied. In such cases, the osteogenic composition may be stabilized for transport and storage. The osteogenic material can be provided as a putty that can be retained in and about the implant assembly. The osteogenic putty is a moldable, flowable material that sets up to a semi-rigid form at about body temperature. The intervertebral implant with the osteogenic material is then inserted into a prepared disc space. The osteogenic material can also include a reinforcement component such as bone chips, preferably cortical bone chips. Examples of osteogenic material suitable for use with this invention include, but are not limited to: OSTEOFIL, which is commercially available from Regeneration Technologies, Inc. of Alachua, Florida; GRAFTON CRUNCH available from Osteotech of Eatontown, NJ and ALLOMATRIX, available from Allosource of Denver, Colorado.

The present invention contemplates modifications as would occur to those skilled in the art. It is also contemplated that processes embodied in the present invention can be altered, rearranged, substituted, deleted, duplicated, combined, or added to other processes as would occur to those skilled in the art without departing from the spirit of the present invention. In addition, the various stages, steps, procedures, techniques, phases, and operations within these processes may be altered, rearranged, substituted, deleted, duplicated, or combined as would occur to those skilled in the art. All publications, patents, and patent applications cited in this specification are herein incorporated by reference as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference and set forth in its entirety herein.

Further, any theory of operation, proof, or finding stated herein is meant to further enhance understanding of the present invention and is not intended to make the scope of the present invention dependent upon such theory, proof, or finding.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is considered to be illustrative and not restrictive in character, it is understood that only the preferred embodiments have been shown

and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. An orthopedic implant for a bone structure, said implant comprising a deformable body formed of a shape memory polymeric material, said body provided in a first configuration and capable of deforming to a second configuration upon application of selected stimuli, wherein said second conformation at least a portion of said body matingly conforms to a portion of the bone structure.

2. The implant of claim 1 wherein the body in the first configuration has a first external volume and in the second configuration has a second external volume greater than the first external volume.

3. The implant of claim 1 wherein the body in the first configuration has a first external volume and the body in the second configuration has a second external volume less than the first external volume.

4. The implant of claim 1 wherein the body defines bone plate.

5. The implant of claim 1 wherein the body defines a bone spacer.

6. The implant of claim 1 wherein the body includes an internal cavity for receipt of an osteogenic material.

7. The implant of claim 1 wherein the body defines a flexible connecting member between two or more adjacent bone portions.

8. The implant of claim 1 wherein said body is provided in an original configuration.

9. The implant of claim 8 wherein said second confirmation is substantially equivalent to said original configuration.

10. The implant of claim 1 wherein the body deforms to said second configuration upon implantation.

11. The implant of claim 1 wherein said body in said second configuration promotes fixation of two or more bone portions.

12. The implant of claim 1 wherein said body contacts two or more adjacent bone portions and in said second configuration permits articulation between the two or more adjacent bone portions.

13. The implant of claim 1 wherein said body in said first configuration is secured to one or more bone portions prior to deforming to the second configuration.

14. The implant of claim 1 wherein the bone structure includes a cavity and said second configuration matingly conforms to the cavity in the bone structure.

15. The implant of claim 1 wherein the shape memory polymeric material is elastic at a deformation temperature and said selected stimuli includes heating the body to a temperature equal or greater than the deformation temperature.

16. The implant of claim 15 wherein the deformation temperature is between about 38° C and about 65° C.

17. The implant of claim 15 wherein the deformation temperature is between about ambient temperature and 65° C.

18. The implant of claim 1 wherein the shaped memory polymeric material is biodegradable.

19. The implant of claim 1 wherein the shaped memory polymeric material is non-biodegradable.

20. The implant of claim 1 wherein the shaped memory polymeric material is selected from the group consisting of: polylactide, polyglycolide, poly(lactide-co-glycolide), polyurethane, poly(ethylene-co-vinyl acetate), poly(ethylene-co-propylene), poly(ethylene-co-propylene-co-diene), poly(ε-caprolactone), poly(β-hydroxybutyrate), poly(β-hydroxybutyrate-co-hydroxyvalerate), poly(methacrylate), poly(methyl methylacrylate), poly(acrylate), and mixtures, copolymers and blends thereof.

21. An orthopedic implant for two or more adjacent bone portions said implant comprising a body formed of a material comprising a shape memory polymer, said body provided in a first configuration and adapted to bear against at least one of said adjacent bone portions, wherein said body deforms upon application of selected stimuli to a second configuration to apply a force to said adjacent bone portions.

22. The implant of claim 21 wherein said force is a compressive force on the adjacent bone portions.

23. The implant of claim 21 wherein said body exhibits a desired tensile strength to replace a tendon or ligament for said two or more adjacent bone portions.

24. The implant of claim 21 wherein the implant includes a bone plate.

25. The implant of claim 21 wherein the body defines a bone spacer.

26. The implant of claim 21 wherein the body defines a flexible connective member between the adjacent bone portions.

27. The implant of claim 21 wherein the body comprises a cavity for receipt of an osteogenic material.

28. The implant of claim 21 wherein said body in said second configuration promotes fixation of the adjacent bone portions.

29. The implant of claim 21 wherein said body permits articulation between adjacent bone portions.

30. The implant of claim 21 wherein the shape memory polymer is elastic at a deformation temperature and said selected stimuli includes heating the body to a temperature equal or greater than the deformation temperature.

31. The implant of claim 21 the deformation temperature is between about 38° C and about 65° C.

32. The implant of claim 21 wherein the deformation temperature is between about ambient temperature and 65° C.

33. The implant of claim 21 wherein the shape memory polymer is biodegradable.

34. The implant of claim 21 wherein the shape memory polymer is non-biodegradable.

35. The implant of claim 21 wherein the shaped memory polymeric material is selected from the group consisting of: polylactide, polyglycolide, poly(lactide-co-glycolide), polyurethane, poly(ethylene-co-vinyl acetate), poly(ethylene-co-propylene), poly(ethylene-co-propylene-co-diene), poly(ε-caprolactone), poly(β-hydroxybutyrate), poly(β-hydroxybutyrate-co-hydroxyvalerate), poly(methacrylate), poly(methyl methylacrylate), poly(acrylate), and mixtures, copolymers and blends thereof.

36. An orthopedic implant comprising a deformable body formed of a shape memory polymeric material and comprising at least one surface adapted to bear against bone tissue wherein said body is provided in a first configuration and upon heating to a deformation temperature said body deforms to a second configuration.

37. The implant of claim 36 wherein the body in the first configuration has a first external volume and in the second configuration has a second external volume greater than the first external volume.

38. The implant of claim 36 wherein the body in the first configuration has a first external volume and the body in the second configuration has a second external volume less than the first external volume.

39. The implant of claim 36 wherein the body defines bone plate.

40. The implant of claim 36 wherein the body defines bone spacer.

41. The implant of claim 36 wherein the body defines a flexible connective member.

42. The implant of claim 36 wherein said body is provided in an original configuration.

43. The implant of claim 36 wherein the body self deforms to said second configuration upon implantation.

44. The implant of claim 36 wherein the deformation temperature is between about 38° C and about 65° C.

45. The implant of claim 36 wherein the deformation temperature is between about ambient temperature and 65° C.

46. The implant of claim 36 wherein said body in said second configuration permits articulation between adjacent bone portions.

47. The implant of claim 36 wherein said second configuration matingly conforms to a cavity in the bone tissue.

48. The implant of claim 36 wherein the shaped memory polymeric material is biodegradable.

49. The implant of claim 36 wherein the shaped memory polymeric material is non-biodegradable.

50. An orthopedic implant for bone tissue said implant comprising body formed of a material comprising a shape memory polymer provided to elastically deform at a deformation temperature, said body provided in a first configuration selected to facilitate implantation and deformable to a second configuration upon heating to a temperature equal to or greater than the deformation temperature, said second configuration provided to facilitate orthopedic treatment.

51. The implant of claim 50 wherein the body in the first configuration has a first external volume and in the second configuration has a second external volume greater than the first external volume.

52. The implant of claim 50 wherein the body in the first configuration has a first external volume and the body in the second configuration has a second external volume less than the first external volume.

53. The implant of claim 50 wherein the body defines a bone spacer.

54. The implant of claim 50 wherein the body defines bone plate.

55. The implant of claim 50 wherein the body defines a flexible connective member.

56. The implant of claim 55 wherein the body connects the bone tissue to a second tissue selected from the group consisting of: bone tissue, ligament tissue, tendon tissue and cartilage tissue.

57. The implant of claim 55 wherein the body is adapted to replace a portion of ligament tissue, tendon tissue or cartilage tissue.

58. The implant of claim 55 wherein the body includes tissue promoting growth factors.

59. The implant of claim 50 wherein the body self deforms to said second configuration upon implantation.

60. The implant of claim 50 wherein said body is provided in an original configuration.

61. The implant of claim 50 wherein the deformation temperature is between about 38° C and about 65° C.

62. The implant of claim 50 wherein the deformation temperature is between about ambient temperature and 65° C.

63. The implant of claim 50 wherein the deformation temperature is below normal body temperature.

64. The implant of claim 50 wherein said body in said second configuration permits articulation between adjacent bone portions.

65. The implant of claim 50 wherein said second configuration matingly conforms to a cavity in the bone tissue.

66. The implant of claim 50 wherein the shaped memory polymeric material is biodegradable.

67. The implant of claim 50 wherein the shaped memory polymeric material is non-biodegradable.

68. A spacer for insertation into a spine, said spacer formed of a material including a shape memory polymer and movable between a first configuration and a second configuration by action of the shape memory polymer.

69. The spacer of claim 68 provided in an original configuration.

70. The spacer of claim 69 wherein the second configuration is substantially equivalent to said original configuration.

71. The spacer of claim 68 wherein said second configuration is larger than said first configuration.

72. The spacer of claim 68 inserted into a disc space.

73. The spacer of claim 68 inserted into a vertebral body.

74. An orthopedic implant comprising a body adapted to contact a vertebral bone and said body formed from a material comprising a shape memory polymer and movable between a first configuration and a second configuration by action the shape memory polymer.

75. The implant of claim 75 wherein said body defines a spacer.

76. The implant of claim 75 wherein said body defines a bone plate.

77. The implant of claim 75 wherein said body defines a flexible connective member between the vertebral bone and a second tissue.

78. The implant of claim 75 wherein the second tissue comprises bone tissue.

79. The implant of claim 75 wherein the second tissue comprises ligament tissue.

80. The implant of claim 75 wherein the second tissue comprises tendon tissue.

81. A method of orthopedic treatment of a bone defect, said method comprising:

selecting an orthopedic implant comprising a deformable body provided in a first configuration and formed of a shape memory polymeric material

contacting said implant to the bone defect;

stimulating said implant to deform said body to a second configuration.

82. The method of claim 81 wherein said shape memory polymeric material is provided to elastically deform at a deformation temperature and wherein said stimulating comprises heating said shape memory polymeric material to a temperature equal to or greater than the deformation temperature.

83. The method of claim 81 wherein the implant contacts a bone defect prior to deformation.

84. The method of claim 81 wherein the implant deforms prior to contacting the bone defect.

85. The method of claim 81 wherein stimulating induces the body to expand.

86. The method of claim 81 wherein stimulating induces the body to contract.

87. A method of preparing a self-forming orthopedic implant, said method comprising:

fabricating an implant from a shape memory polymeric material, wherein said implant comprises a deformable body provided in an original configuration;

deforming said body to a first configuration; and

stimulating said body to induce the body to revert to the original configuration or a second configuration.

88. The method of claim 87 wherein the second configuration is substantially equivalent thereto to original configuration.

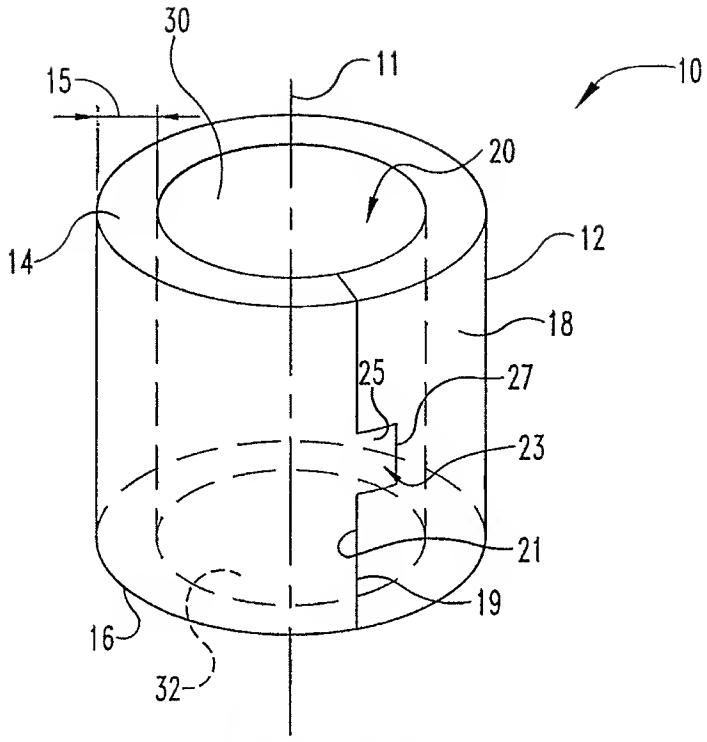

Fig. 1

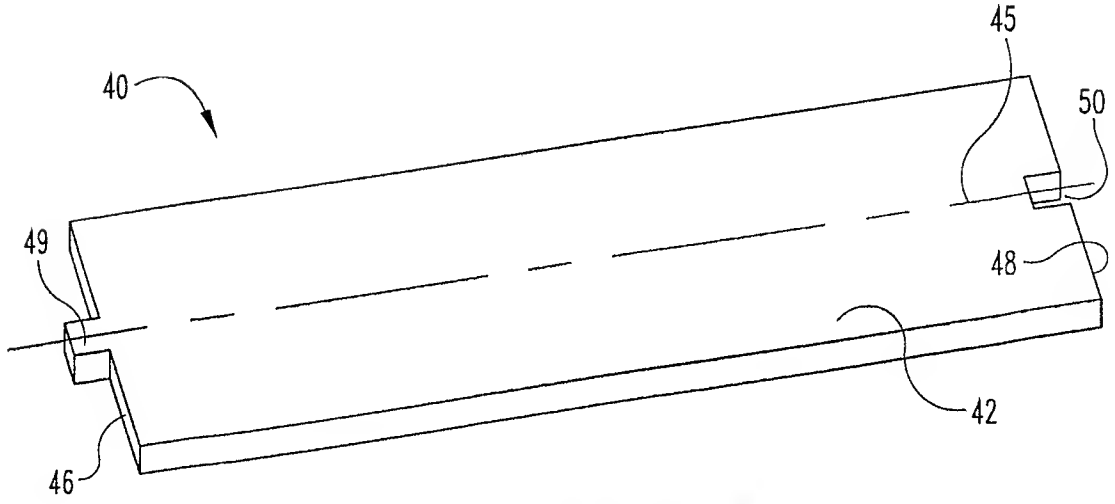

Fig. 2

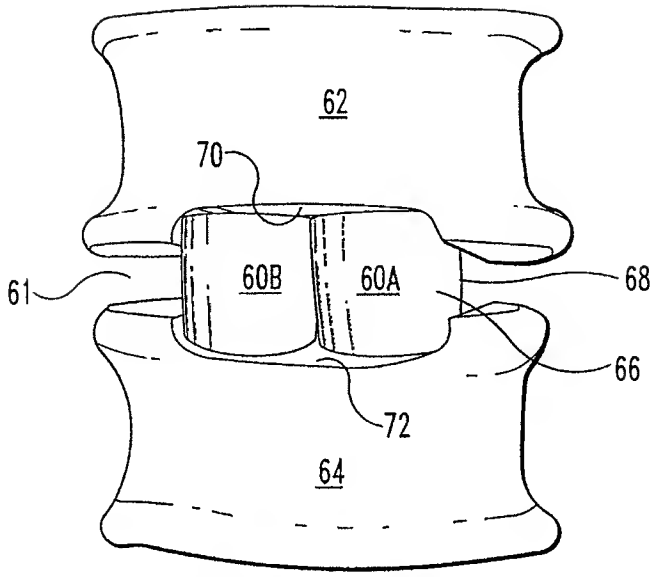

Fig. 3

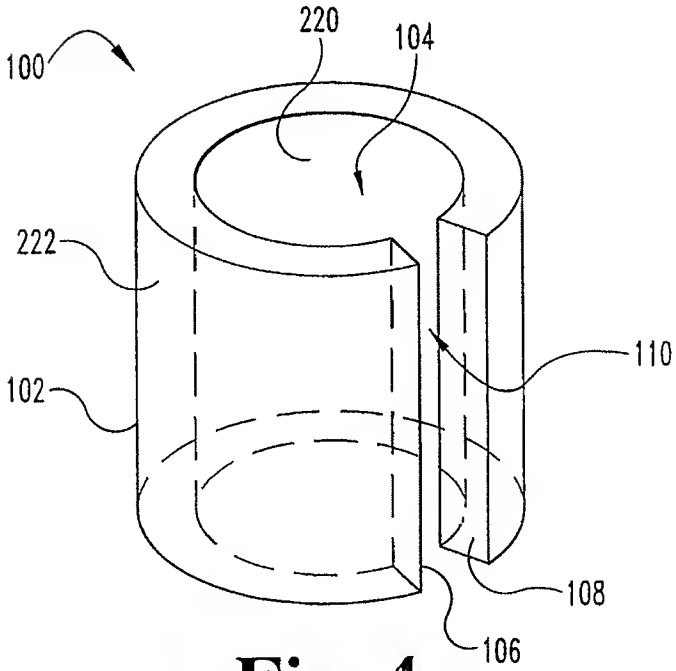

Fig. 4

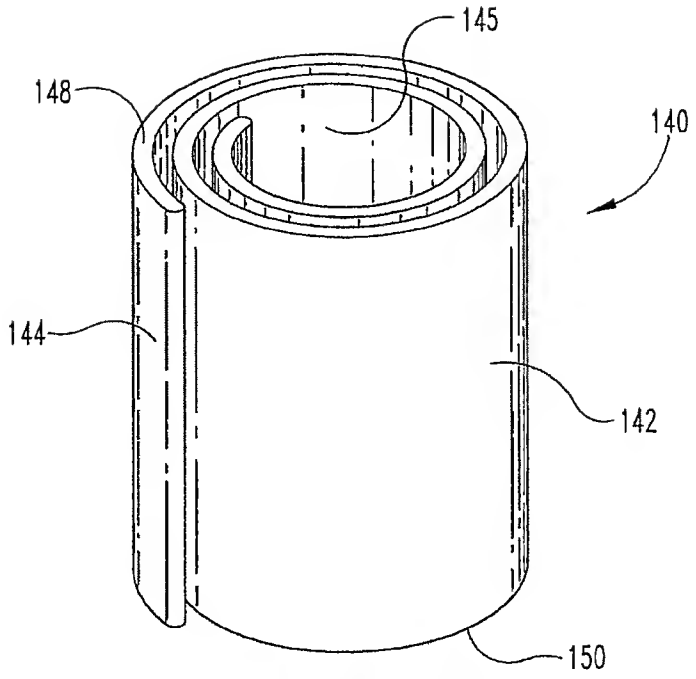

Fig. 5

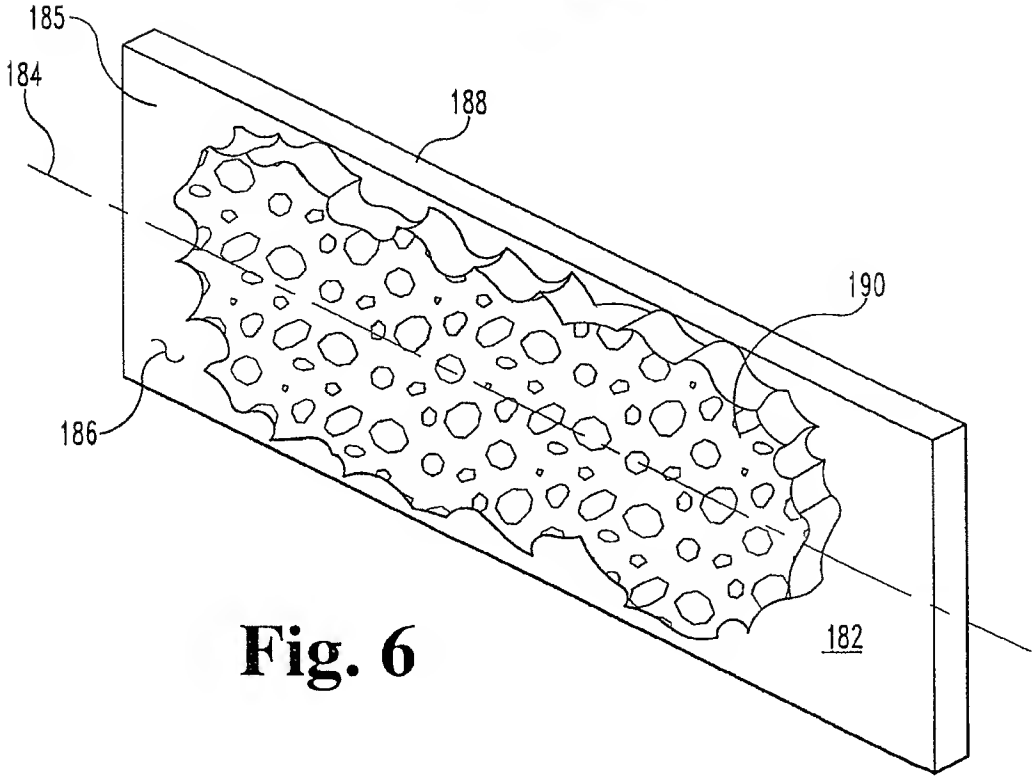

Fig. 6

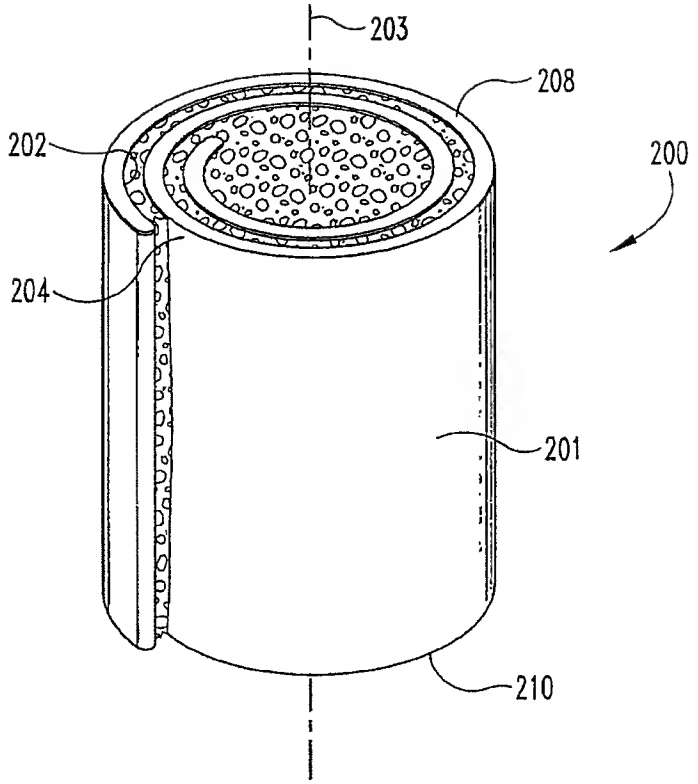

Fig. 7

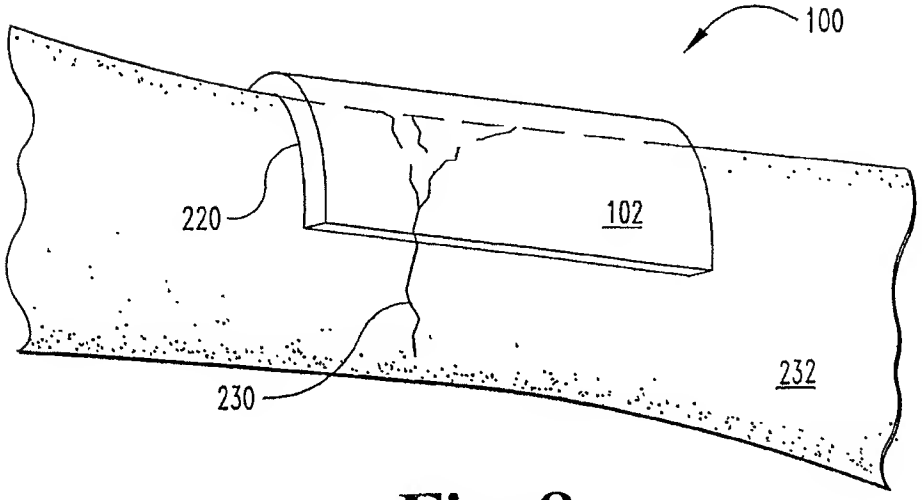

Fig. 8

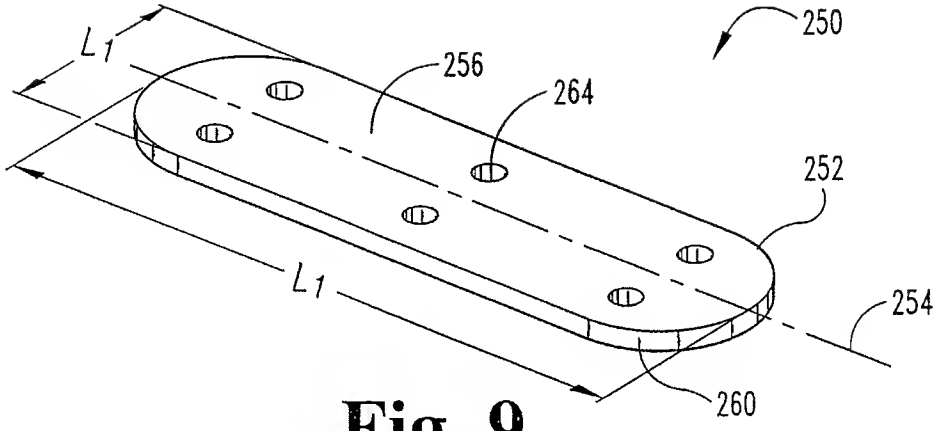

Fig. 9

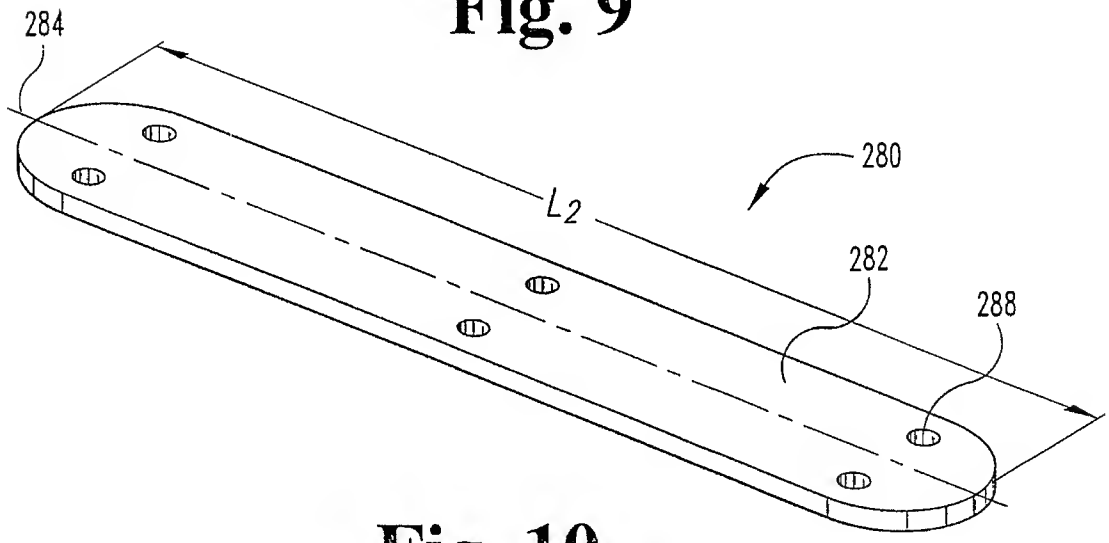

Fig. 10

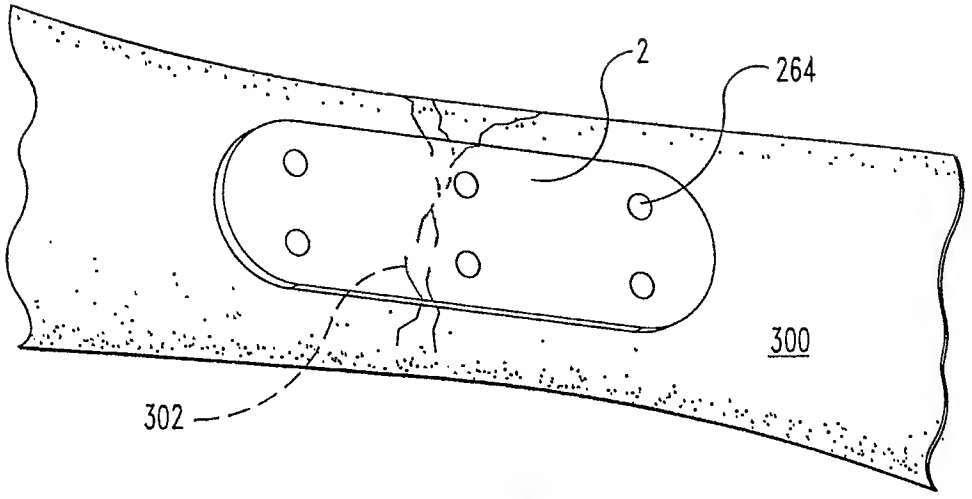

Fig. 11

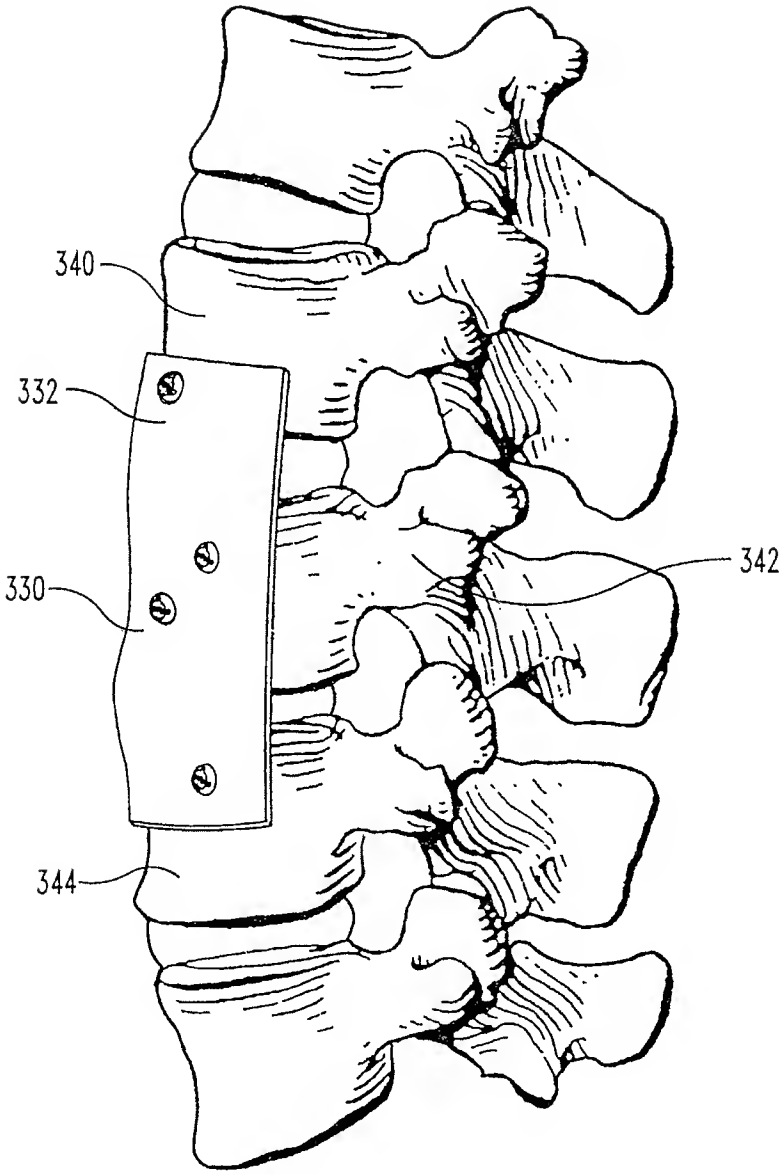

Fig. 12